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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,108	04/06/2000	Kenneth Eliot Sherman		7634

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/544,108	SHERMAN, KENNETH ELIOT	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-17 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3-6* is/are allowed.

6)☒ Claim(s) *1,7,8,10-17 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *May 6, 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 April 2006 has been entered.

Amendments filed on January 4, 2006 and March 3, 2006, and the Declaration under 37 CFR § 1.132 filed on January 4, 2006 have been considered and have been entered.

Claims 1, 3-8, 10-17, 19-24 are pending in this application. Claim 1 and 16 has been amended. Claims 1, 3-8, 10-17, 19-24 are under consideration in this Action.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Art Unit 1648.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 3-8, 10-17, 19-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the Declaration under 37 CFR § 1.132 submitted on January 4, 2006.

Double Patenting

The provisional obviousness-type double patenting rejection of record in the Office action of March 29, 2002 has been withdrawn upon further consideration.

New rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite "thymosin fragment" and "immune system potentiating fragments of thymosin". The Applicant did not demonstrate possession of the large genus encompassed by "thymosin fragment" or "immune system potentiating fragments of thymosin". The specification does not provide a structure/function correlation for the "thymosin fragment" or "immune system potentiating fragments of thymosin". There is a lack of a representative number of species of "thymosin fragment" and "immune system potentiating fragments of thymosin" that would

reasonably represent the claimed genus. Thus, the Applicant does not have the possession of the claimed genus.

The skilled artisan would not be able to practice the current invention without further guidance as to what is the actual structure of the thymosin fragments.

[Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision what would be the actual structure of the thymosin fragment and the skilled artisan would not know which thymosin fragments are the immune system potentiating fragments. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 8, 10-17, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (of record in IDS of May 6, 2002) in view of Hoofnagle et al. (of record in IDS of May 6, 2002) and further in view of Horecker (US Patent 4,614,731).

Claims are drawn to a composition comprising a pharmaceutical dosage unit of thymosin or a thymosin fragment and an anti-hepatitis C viral effective amount of at least one α-interferon. The invention provides that the alpha interferon may comprise alpha 2-B interferon, and that thymosin or its fragment may comprise thymosin alpha-1, or thymosin fraction 5 (TF5). Applicant also claim specific dosages within the composition for alpha interferon,thymosin alpha-1 and TF5.

Huang et al. teach the pharmaceutical combination of interferon and thymosin for treating hepatitis B in human patients. Since the composition disclosed by Huang et al. showed antiviral effects in human patients, the amount of composition are believed to be the same as those claimed, and the combination of Huang et al. is deemed to anticipate the claimed subject matter, regardless of the intended use which is not given patentable weight. Any properties of the composition of Huang et al. are expected to be present in the instantly claimed composition, even if those properties were not recognized by Huang et al. such as its anti-hepatitis C activity.

Huang et al. does not specify which particular thymosin or interferon was used in the composition. Hoofnagle et al., teach using recombinant alpha 2-b interferon (see p.261) for treatment of HCV infection. Hoofnagle et al. teach that the range of the dosage unit of alpha 2-b interferon given to the patient is 2 to 5 million units daily, which overlaps the range of the dosage units claimed which is 1 to 3.

Neither Huang et al. or Hoofnagle et al. teach the specific type of thymosin in coadministration with interferon. Horecker teach that thymosin fraction 5 (TF5) is effective in increasing T cell numbers and normalizing the immune function (see column 1, lines 15-22).

It would have been obvious to prepare a pharmaceutical composition comprising Hoofnagle's alpha 2-b interferon in combination with thymosin fraction 5 (TF5) of Horecker. One of ordinary skill in the art at the time the invention was made would have been motivated to use the particular interferon (alpha 2-b) and thymosin (TF5) because Huang et al. teaches the pharmaceutical combination of interferon and thymosin for anti-HCV therapy. Further, Hoofnagle et al., teach using recombinant alpha 2-b interferon (see p.261) for treatment of HCV infection, and Horecker teaches that thymosin fraction 5 (TF5) is effective in increasing T cell numbers and normalizing the immune function (see column 1, lines 15-22).

Thus, the skilled artisan would have had a reasonable expectation of success to combine Hoofnagle's alpha 2-b interferon in a pharmaceutical composition with thymosin fraction 5 (TF5) of Horecker.

Huang et al. does not specifically teach administering particular doses of thymosin and interferon, however it would have been well within the ability of the artisan to optimize the amounts of interferon and thymosin for treatment as suggested by Hoofnagle et al. (see page 262, last paragraph). Thus, one of ordinary skill in the art would be able to optimize the amounts of interferon and thymosin for treatment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner
June 9, 2006

Stacy B. Chen 6/9/06

Stacy B. Chen
Primary Examiner